DEPARTMEN

Office of the Secretary

21 CFR Ch. I

25 CFR Ch. V

42 CFR Chs. I-V

45 CFR Subtitle A; Subtitle B, Chs. II, III, and XIII

Regulatory Agenda

AGENCY: Office of the Secretary, HHS.

ACTION: Semiannual Regulatory Agenda.

SUMMARY: The Regulatory Flexibility Act of 1980 and Executive Order (EO) 12866 require the semiannual issuance of an inventory of rulemaking actions under development throughout the Department, offering for public review summarized information about forthcoming regulatory actions.

FOR FURTHER INFORMATION CONTACT: Karuna Seshasai, Executive Secretary, Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201; (202) 690-5627.

SUPPLEMENTARY INFORMATION: The Department of Health and Human Services (HHS) is the Federal government's lead agency for protecting the health of all Americans and providing essential human services. HHS enhances the health and well-being of Americans by promoting effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services.

This Agenda presents the regulatory activities that the Department expects to undertake in the foreseeable future to advance this mission. The purpose of the Agenda is to encourage more effective public participation in the regulatory process. The regulatory actions forecasted in this Agenda reflect the priorities of HHS Secretary Xavier Becerra and the Biden-Harris Administration. Accordingly, this Agenda contains rulemakings aimed at tackling the coronavirus disease 2019 (COVID-19) pandemic, building and expanding access to affordable health care, addressing health disparities and promoting equity, and boosting the wellbeing of children and families, among other policy priorities.

The rulemaking abstracts included in this paper issue of the **Federal Register** cover, as required by the Regulatory Flexibility Act of 1980, those prospective HHS rulemakings likely to have a significant

economic impact on a substantial number of small entities. The Department's complete Regulatory Agenda is accessible online at http://www.RegInfo.gov.

Karuna Seshasai,

Executive Secretary to the Department.

Office of the Secretary—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
260	Limiting the Effect of Exclusions Implemented Under the Social Security Act **(Rulemaking Resulting From a Section 610 Review)**	0991–AC11

Office for Civil Rights—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
261	Rulemaking on Discrimination on the Basis of Disability in Critical Health and Human Services Programs or Activities **(Rulemaking Resulting From a Section 610 Review) (Reg Plan Seq No. 45)**	0945–AA15

References in boldface appear in The Regulatory Plan in part II of this issue of the **Federal Register.**

Substance Abuse and Mental Health Services Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
262	Treatment of Opioid use Disorder With Extended Take Home Doses of Methadone **(Reg Plan Seq No. 50)**	0930–AA39

References in boldface appear in The Regulatory Plan in part II of this issue of the **Federal Register.**

Centers for Disease Control and Prevention—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
263	Control of Communicable Diseases; Foreign Quarantine	0920–AA75

Food and Drug Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
264	National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers	0910–AH11
265	Nicotine Toxicity Warnings	0910–AH24
266	Certain Requirements Regarding Prescription Drug Marketing (203 Amendment)	0910–AH56
267	Medication Guide; Patient Medication Information	0910–AH68
268	Requirements for Tobacco Product Manufacturing Practice	0910–AH91
269	Administrative Detention of Tobacco Products	0910–AI05

270	Nutrient Content Claims, Definition of Term: Healthy **(Reg Plan Seq No. 53)**	0910–AI13
271	Revocation of Uses of Partially Hydrogenated Oils in Foods	0910–AI15
272	Tobacco Product Standard for Characterizing Flavors in Cigars **(Reg Plan Seq No. 56)**	0910–AI28
273	Conduct of Analytical and Clinical Pharmacology, Bioavailability and Bioequivalence Studies **(Reg Plan Seq No. 57)**	0910–AI57
274	Additional Amendments to the Final Rule Regarding the List of Bulk Substances that can be used to Compound Drug Products in Accordance With Section 503A of the Federal Food, Drug and Cosmetic Act **(Section 610 Review)**	0910–AI70

References in boldface appear in The Regulatory Plan in part II of this issue of the **Federal Register.**

Food and Drug Administration—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
275	Direct-to-Consumer Prescription Drug Advertisements: Presentation of the Major Statement in a Clear, Conspicuous, Neutral Manner in Advertisements in Television and Radio Format	0910–AG27
276	Sunlamp Products; Amendment to the Performance Standard	0910–AG30
277	Mammography Quality Standards Act	0910–AH04
278	General and Plastic Surgery Devices: Restricted Sale, Distribution, and Use of Sunlamp Products	0910–AH14

279	Laboratory Accreditation for Analyses of Foods	0910–AH31
280	Amendments to the List of Bulk Drug Substances That Can Be Used To Compound Drug Products in Accordance With Section 503A of the Federal Food, Drug, and Cosmetic Act	0910–AH81

Food and Drug Administration—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
281	Requirements For Additional Traceability Records For Certain Foods	0910–AI44
282	Postmarketing Safety Reporting Requirements, Pharmacovigilance Plans, and Pharmacovigilance Quality Systems for Human Drug and Biological Products	0910–AI61

Centers for Medicare & Medicaid Services—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
283	Administrative Simplification: Modifications to NCPDP Retail Pharmacy Standards (CMS-0056)	0938–AU19
284	Medicare Advantage and Medicare Prescription Drug Benefit Program Payment Policy (CMS-4198)	0938–AU59
285	CY 2023 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS-1770) **(Section 610 Review)**	0938–AU81

286	CY 2023 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS-1772) **(Section 610 Review)**	0938–AU82
287	Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals; the Long-Term Care Hospital Prospective Payment System; and FY 2023 Rates (CMS-1771-P) **(Section 610 Review)**	0938–AU84
288	Transitional Coverage for Emerging Technologies (CMS-3421)	0938–AU86
289	Requirements for Rural Emergency Hospitals (CMS-3419) **(Section 610 Review) (Reg Plan Seq No. 66)**	0938–AU92

References in boldface appear in The Regulatory Plan in part II of this issue of the **Federal Register.**

Centers for Medicare & Medicaid Services—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
290	Durable Medical Equipment Fee Schedule, Adjustments to Resume the Transitional 50/50 Blended Rates to Provide Relief in Non-Competitive Bidding Areas (CMS-1687) **(Section 610 Review)**	0938–AT21
291	Requirements Related to Surprise Billing; Part II (CMS-9908)	0938–AU62
292	Omnibus COVID-19 Health Care Staff Vaccination (CMS-3415) **(Section 610 Review) (Reg Plan Seq No. 69)**	0938–AU75

References in boldface appear in The Regulatory Plan in part II of this issue of the **Federal Register.**

Centers for Medicare & Medicaid Services—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
293	Most Favored Nation (MFN) Model (CMS-5528) **(Section 610 Review)**	0938–AT91
294	Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Policy Issues and Level II of the Healthcare Common Procedure Coding System (HCPCS) (CMS-1738) **(Section 610 Review)**	0938–AU17
295	Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals; the Long-Term Care Hospital Prospective Payment System; and FY 2022 Rates (CMS-1752) **(Section 610 Review)**	0938–AU44

Centers for Medicare & Medicaid Services—Completed Actions

Sequence Number	Title	Regulation Identifier Number
296	Requirements for Long-Term Care Facilities: Regulatory Provisions to Promote Increased Safety (CMS-3347) **(Completion of a Section 610 Review)**	0938–AT36
297	CY 2022 Home Health Prospective Payment System Rate Update, Home Infusion Therapy Services, and Quality Reporting Requirements (CMS-1747) **(Completion of a Section 610 Review)**	0938–AU37
298	FY 2022 Inpatient Psychiatric Facilities Prospective Payment System Rate and Quality Reporting Updates (CMS-1750) **(Completion of a Section 610 Review)**	0938–AU40

299	CY 2022 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS-1751) **(Completion of a Section 610 Review)**	0938–AU42
300	CY 2022 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS-1753) **(Completion of a Section 610 Review)**	0938–AU43
301	Requirements Related to Surprise Billing; Part I (CMS-9909)	0938–AU63

Administration for Children and Families—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
302	Updating Native Employment Works Requirements **(Rulemaking Resulting From a Section 610 Review)**	0970–AC83

Department of Health and Human Services (HHS)	**Proposed Rule Stage**
Office of the Secretary (OS)	

260. LIMITING THE EFFECT OF EXCLUSIONS IMPLEMENTED UNDER THE SOCIAL SECURITY ACT (RULEMAKING RESULTING FROM A SECTION 610 REVIEW)

Legal Authority: 5 U.S.C. 301; 31 U.S.C. 6101

Abstract: Exclusions implemented under the Social Security Act prevent individuals convicted of certain crimes or individuals whose health care licenses have been revoked from participating in Federal health care programs. Instead of only being barred from participating in all Federal healthcare programs, certain

regulatory provisions have resulted in these type of exclusion actions being given an overly broad government-wide effect, and excluded parties have been barred from participating in all Federal procurement and non-procurement actions. However, because Social Security Act exclusions are not issued under an agency's suspension and debarment authority, they do not stop individuals from participating in all Federal procurement and non-procurement actions. For an agency to bar individuals from participating in all procurement and non-procurement activities, it must exercise its suspension and debarment authority under the Federal Acquisition Regulation or the Nonprocurement Common Rule. This rulemaking would remove the regulatory provisions at issue, in order to align the regulation with the intent of the Social Security Act and current practice.

Timetable:

Action	Date	FR Cite
NPRM	12/00/21	

Regulatory Flexibility Analysis Required: No

Agency Contact: Tiffani Redding, Program Analyst, Department of Health and Human Services, Office of the Secretary, 200 Independence Avenue SW, Washington, DC 20201

Phone: 202 205–4321

Email: tiffani.redding@hhs.gov

RIN: 0991–AC11

Department of Health and Human Services (HHS)	Proposed Rule Stage
Office for Civil Rights (OCR)	

261. RULEMAKING ON DISCRIMINATION ON THE BASIS OF DISABILITY IN CRITICAL HEALTH AND HUMAN SERVICES PROGRAMS OR ACTIVITIES (RULEMAKING RESULTING FROM A SECTION 610 REVIEW)

Regulatory Plan: This entry is Seq. No. 45 in part II of this issue of the **Federal Register.**

RIN: 0945–AA15

Department of Health and Human Services (HHS)	**Proposed Rule Stage**
Substance Abuse and Mental Health Services Administration (SAMHSA)	

262. • TREATMENT OF OPIOID USE DISORDER WITH EXTENDED TAKE HOME DOSES OF METHADONE

Regulatory Plan: This entry is Seq. No. 50 in part II of this issue of the **Federal Register.**

RIN: 0930–AA39

Department of Health and Human Services (HHS)	**Final Rule Stage**
Centers for Disease Control and Prevention (CDC)	

263. CONTROL OF COMMUNICABLE DISEASES; FOREIGN QUARANTINE

Legal Authority: 42 U.S.C. 264; 42 U.S.C. 265

Abstract: This rulemaking amends current regulation to enable CDC to require airlines to collect and provide to CDC certain data elements regarding passengers and crew arriving from foreign countries under certain circumstances.

Timetable:

Action	Date	FR Cite
Interim Final Rule Effective	02/07/20	
Interim Final Rule	02/12/20	85 FR 7874
Interim Final Rule Comment Period End	03/13/20	
Final Action	09/00/22	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Ashley C. Altenburger JD, Public Health Analyst, Department of Health and Human Services, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS: H 16–4, Atlanta, GA 30307

Phone: 800 232–4636

Email: dgmqpolicyoffice@cdc.gov

RIN: 0920–AA75

Department of Health and Human Services (HHS)	Proposed Rule Stage
Food and Drug Administration (FDA)	

264. NATIONAL STANDARDS FOR THE LICENSURE OF WHOLESALE DRUG DISTRIBUTORS AND THIRD–PARTY LOGISTICS PROVIDERS

Legal Authority: Pub. L. 113–54

Abstract: The rulemaking, once finalized, will establish standards for State licensing of prescription drug wholesale distributors and third-party logistics providers. The rulemaking will also establish a Federal system for wholesale drug distributor and third-party logistics provider licensing for use in the absence of a State licensure program.

Timetable:

Action	Date	FR Cite
NPRM	12/00/21	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Aaron Weisbuch, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Building 51, Room 4261, 10903 New Hampshire Avenue, Silver Spring, MD 20993

Phone: 301 796–9362

Email: aaron.weisbuch@fda.hhs.gov

RIN: 0910–AH11

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265. NICOTINE TOXICITY WARNINGS

Legal Authority: 21 U.S.C. 301 et seq.; 21 U.S.C. 331; 21 U.S.C. 371; 21 U.S.C. 387f; ...

Abstract: This rule would establish acute nicotine toxicity warning requirements for liquid nicotine and nicotine-containing e-liquid(s) that are made or derived from tobacco and intended for human consumption, and potentially for other tobacco products including, but not limited to, novel tobacco products such as dissolvables, lotions, gels, and drinks. This action is intended to increase consumer awareness and knowledge of the risks of acute toxicity due to accidental nicotine exposure from nicotine-containing e-liquids in tobacco products.

Timetable:

Action	Date	FR Cite
NPRM	10/00/22	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Samantha LohCollado, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Tobacco Products, 10903 New Hampshire Avenue, Document Control Center, Building 71, Room G335, Silver Spring, MD 20993

Phone: 877 287–1373

Email: ctpregulations@fda.hhs.gov

RIN: 0910–AH24

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266. CERTAIN REQUIREMENTS REGARDING PRESCRIPTION DRUG MARKETING (203 AMENDMENT)

Legal Authority: Pub. L. 113–54

Abstract: The Food and Drug Administration (FDA) is amending the regulations at 21 CFR 203 to remove provisions no longer in effect and incorporate conforming changes following enactment of the Drug Supply Chain Security Act (DSCSA). In this proposed rulemaking, the Agency is amending the regulations to clarify provisions and avoid causing confusion with the new standards for wholesale distribution established by DSCSA.

Timetable:

Action	Date	FR Cite
NPRM	01/00/22	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Aaron Weisbuch, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Building 51, Room 4261, 10903 New Hampshire Avenue, Silver Spring, MD 20993

Phone: 301 796–9362

Email: aaron.weisbuch@fda.hhs.gov

RIN: 0910–AH56

267. MEDICATION GUIDE; PATIENT MEDICATION INFORMATION

Legal Authority: 21 U.S.C. 321 et seq.; 42 U.S.C. 262; 42 U.S.C. 264; 21 U.S.C. 371

Abstract: The proposed rule would amend FDA medication guide regulations to require a new form of patient labeling, Patient Medication Information, for submission to and review by FDA for human prescription drug products and certain blood products used, dispensed, or administered on an outpatient basis. The proposed rule would include requirements for Patient Medication Information development and distribution. The proposed rule would require clear and concisely written prescription drug product information presented in a consistent and easily understood format to help patients use their prescription drug products safely and effectively.

Timetable:

Action	Date	FR Cite
NPRM	02/00/22	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Chris Wheeler, Supervisory Project Manager, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, Building 51, Room 3330, Silver Spring, MD 20993

Phone: 301 796–0151

Email: chris.wheeler@fda.hhs.gov

RIN: 0910–AH68

268. REQUIREMENTS FOR TOBACCO PRODUCT MANUFACTURING PRACTICE

Legal Authority: 21 U.S.C. 371; 21 U.S.C. 387b; 21 U.S.C. 387f

Abstract: The rule is proposing to establish tobacco product manufacturing practice (TPMP) requirements for manufacturers of finished and bulk tobacco products. This proposed rule, if finalized, would set forth requirements for the manufacture, pre-production design validation, packing, and storage

of a tobacco product. This proposal would help prevent the manufacture and distribution of contaminated and otherwise nonconforming tobacco products. This proposed rule provides manufacturers with flexibility in the manner in which they comply with the proposed requirements while giving FDA the ability to enforce regulatory requirements, thus helping to assure the protection of public health.

Timetable:

Action	Date	FR Cite
NPRM	03/00/22	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Matthew Brenner, Senior Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Tobacco Products, 10903 New Hampshire Avenue, Document Control Center, Building 71, Room G335, Silver Spring, MD 20993

Phone: 877 287–1373

Email: ctpregulations@fda.hhs.gov

RIN: 0910–AH91

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269. ADMINISTRATIVE DETENTION OF TOBACCO PRODUCTS

Legal Authority: 21 U.S.C. 334; 21 U.S.C. 371

Abstract: FDA is proposing regulations to establish requirements for the administrative detention of tobacco products. This proposal would allow FDA to administratively detain tobacco products encountered during inspections that an officer or employee conducting the inspection has reason to believe are adulterated or misbranded. The intent of administrative detention is to protect public health by preventing the distribution or use of tobacco products encountered during inspections that are believed to be adulterated or misbranded.

Timetable:

Action	Date	FR Cite

NPRM	07/00/22	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Nathan Mease, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Tobacco Products, 10903 New Hampshire Avenue, Document Control Center, Building 71, Room G335, Silver Spring, MD 20993

Phone: 877 287–1373

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Matthew Brenner, Senior Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Tobacco Products, 10903 New Hampshire Avenue, Document Control Center, Building 71, Room G335, Silver Spring, MD 20993

Phone: 877 287–1373

Email: ctpregulations@fda.hhs.gov

RIN: 0910–AI05

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270. NUTRIENT CONTENT CLAIMS, DEFINITION OF TERM: HEALTHY

Regulatory Plan: This entry is Seq. No. 53 in part II of this issue of the **Federal Register.**

RIN: 0910–AI13

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271. REVOCATION OF USES OF PARTIALLY HYDROGENATED OILS IN FOODS

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 341; 21 U.S.C. 342; 21 U.S.C. 343; 21 U.S.C. 348; 21 U.S.C. 371; 21 U.S.C. 379e

Abstract: In the **Federal Register** of June 17, 2015 (80 FR 34650), we published a declaratory order announcing our final determination that there is no longer a consensus among qualified experts that partially hydrogenated oils (PHOs) are generally recognized as safe (GRAS) for any use in human food. In the **Federal Register** of May 21, 2018 (83 FR 23382), we denied a food additive petition requesting that the food additive regulations be amended to provide for the safe use of PHOs in certain food

applications. We are now proposing to update our regulations to remove all mention of partially hydrogenated oils from FDA's GRAS regulations and as an optional ingredient in standards of identity. We are also proposing to revoke all prior sanctions for uses of PHOs in food.

Timetable:

Action	Date	FR Cite
NPRM	01/00/22	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Ellen Anderson, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, HFS–265, 4300 River Road, College Park, MD 20740

Phone: 240 402–1309

Email: ellen.anderson@fda.hhs.gov

RIN: 0910–AI15

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272. TOBACCO PRODUCT STANDARD FOR CHARACTERIZING FLAVORS IN CIGARS

Regulatory Plan: This entry is Seq. No. 56 in part II of this issue of the **Federal Register.**

RIN: 0910–AI28

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273. CONDUCT OF ANALYTICAL AND CLINICAL PHARMACOLOGY, BIOAVAILABILITY AND BIOEQUIVALENCE STUDIES

Regulatory Plan: This entry is Seq. No. 57 in part II of this issue of the **Federal Register.**

RIN: 0910–AI57

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274. • ADDITIONAL AMENDMENTS TO THE FINAL RULE REGARDING THE LIST OF BULK SUBSTANCES THAT CAN BE USED TO COMPOUND DRUG PRODUCTS IN ACCORDANCE WITH SECTION 503A OF THE FEDERAL FOOD, DRUG AND COSMETIC ACT (SECTION 610 REVIEW)

Legal Authority: 21 U.S.C. 353a; 21 U.S.C. 351; 21 U.S.C. 371(a); 21 U.S.C. 352; 21 U.S.C. 355; ...

Abstract: FDA has issued a regulation creating a list of bulk drug substances (active pharmaceutical ingredients) that can be used to compound drug products in accordance with section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act), although they are neither the subject of an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph nor components of FDA-approved drug products (the 503A Bulks List). The proposed rule will identify certain bulk drug substances that FDA has considered and is proposing to place on the 503A Bulks List and certain bulk drug substances that FDA has considered and is proposing not to include on the 503A Bulks List.

Timetable:

Action	Date	FR Cite
NPRM	11/00/21	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Alexandria Fujsaki, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, Building 51, Room 5169, Center for Drug Evaluation and Research, Silver Spring, MD 20993

Phone: 240 402–4078

RIN: 0910–AI70

Department of Health and Human Services (HHS)	Final Rule Stage
Food and Drug Administration (FDA)	

275. DIRECT–TO–CONSUMER PRESCRIPTION DRUG ADVERTISEMENTS: PRESENTATION OF THE MAJOR STATEMENT IN A CLEAR, CONSPICUOUS, NEUTRAL MANNER IN ADVERTISEMENTS IN TELEVISION AND RADIO FORMAT

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 331; 21 U.S.C. 352; 21 U.S.C. 355; 21 U.S.C. 360b; 21 U.S.C. 371; ...

Abstract: The Food and Drug Administration (FDA) is amending its regulations concerning direct-to-consumer (DTC) advertisements of prescription drugs. Prescription drug advertisements presented through media such as TV and radio must disclose the product's major side effects and contraindications in what is sometimes called the major statement. The rule would revise the regulation to reflect the statutory requirement that in DTC advertisements for human drugs in television or radio format, the major statement relating to side effects and contraindications of an advertised prescription drug must be presented in a clear, conspicuous, and neutral manner. This rule also establishes standards for determining whether the major statement in these advertisements is presented in the manner required.

Timetable:

Action	Date	FR Cite
NPRM	03/29/10	75 FR 15376
NPRM Comment Period End	06/28/10	
NPRM Comment Period Reopened	01/27/12	77 FR 4273
NPRM Comment Period End	02/27/12	
NPRM Comment Period Reopened	03/29/12	77 FR 16973
NPRM Comment Period Reopened End	04/09/12	
Final Rule	09/00/22	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Suzanna Boyle, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, WO 51, Room 3214, Silver Spring, MD 20993

Phone: 240 402–4723

Email: suzanna.boyle@fda.hhs.gov

RIN: 0910–AG27

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276. SUNLAMP PRODUCTS; AMENDMENT TO THE PERFORMANCE STANDARD

Legal Authority: 21 U.S.C. 360ii; 21 U.S.C. 360kk; 21 U.S.C. 393; 21 U.S.C. 371

Abstract: FDA is updating the performance standard for sunlamp products and ultraviolet lamps for use in these products to improve safety, reflect new scientific information, and work towards harmonization with international standards. By harmonizing with the International Electrotechnical Commission, this rule will decrease the regulatory burden on industry and allow the Agency to take advantage of the expertise of the international committees, thereby also saving resources.

Timetable:

Action	Date	FR Cite
NPRM	12/22/15	80 FR 79505
NPRM Comment Period End	03/21/16	
Final Rule	05/00/22	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Ian Ostermiller, Regulatory Counsel, Center for Devices and Radiological Health, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, WO 66, Room 5454, Silver Spring, MD 20993

Phone: 301 796–5678

Email: ian.ostermiller@fda.hhs.gov

RIN: 0910–AG30

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277. MAMMOGRAPHY QUALITY STANDARDS ACT

Legal Authority: 21 U.S.C. 360i; 21 U.S.C. 360nn; 21 U.S.C. 374(e); 42 U.S.C. 263b

Abstract: FDA is amending its regulations governing mammography. The amendments will update the regulations issued under the Mammography Quality Standards Act of 1992 (MQSA) and the Federal Food, Drug, and Cosmetic Act (FD&C Act). FDA is taking this action to address changes in mammography technology and mammography processes that have occurred since the regulations were published in 1997 and to address breast density reporting to patient and healthcare providers.

Timetable:

Action	Date	FR Cite
NPRM	03/28/19	84 FR 11669
NPRM Comment Period End	06/26/19	
Final Rule	03/00/22	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Jean M. Olson, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, Building 66, Room 5506, Silver Spring, MD 20993

Phone: 301 796–6579

Email: jean.olson@fda.hhs.gov

RIN: 0910–AH04

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278. GENERAL AND PLASTIC SURGERY DEVICES: RESTRICTED SALE, DISTRIBUTION, AND USE OF SUNLAMP PRODUCTS

Legal Authority: 21 U.S.C. 360j(e)

Abstract: This rule will apply device restrictions to sunlamp products. Sunlamp products include ultraviolet (UV) lamps and UV tanning beds and booths. The incidence of skin cancer, including melanoma, has been increasing, and a large number of skin cancer cases are attributable to the use of sunlamp products. The devices may cause about 400,000 cases of skin cancer per year, and 6,000 of which are melanoma. Beginning use of sunlamp products at young ages, as well as frequently using

sunlamp products, both increases the risk of developing skin cancers and other illnesses, and sustaining other injuries. Even infrequent use, particularly at younger ages, can significantly increase these risks.

Timetable:

Action	Date	FR Cite
NPRM	12/22/15	80 FR 79493
NPRM Comment Period End	03/21/16	
Final Rule	05/00/22	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Ian Ostermiller, Regulatory Counsel, Center for Devices and Radiological Health, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, WO 66, Room 5454, Silver Spring, MD 20993

Phone: 301 796–5678

Email: ian.ostermiller@fda.hhs.gov

RIN: 0910–AH14

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279. LABORATORY ACCREDITATION FOR ANALYSES OF FOODS

Legal Authority: 21 U.S.C. 350k; 21 U.S.C. 371(a); ...

Abstract: This rule will enable FDA to recognize accreditation bodies that will accredit laboratories to perform analyses of food under certain circumstances to help ensure appropriate use of equipment, personnel, and procedures to conduct reliable analyses. A program for accredited laboratories will increase the number of qualified laboratories eligible to perform testing of food, which will help FDA improve the safety of the U.S. food supply.

Timetable:

Action	Date	FR Cite

NPRM	11/04/19	84 FR 59452
NPRM Comment Period End	03/03/20	
NPRM Comment Period Extended	02/28/20	85 FR 11893
NPRM Comment Period Extended	04/06/20	85 FR 19114
NPRM Comment Period End	07/06/20	
Final Rule	02/00/22	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Stacie Hammack, Chemist, Department of Health and Human Services, Food and Drug Administration, Office of Regulatory Affairs, Food and Feed Laboratory Operations, 60 8th Street NE, Atlanta, GA 30309

Phone: 301 796–5817

Email: stacie.hammack@fda.hhs.gov

RIN: 0910–AH31

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280. AMENDMENTS TO THE LIST OF BULK DRUG SUBSTANCES THAT CAN BE USED TO COMPOUND DRUG PRODUCTS IN ACCORDANCE WITH SECTION 503A OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

Legal Authority: 21 U.S.C. 351; 21 U.S.C. 352; 21 U.S.C. 353a; 21 U.S.C. 355; 21 U.S.C. 371; ...

Abstract: FDA has issued a regulation creating a list of bulk drug substances (active pharmaceutical ingredients) that can be used to compound drug products in accordance with section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act), although they are neither the subject of an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph nor components of FDA-approved drugs (the 503A Bulks List). FDA has proposed to amend the 503A Bulks List by placing five additional bulk drug substances on the list. FDA has also identified 26 bulk drug substances that FDA has

considered and proposed not to include on the 503A Bulks List. Additional substances nominated by the public for inclusion on this list are currently under consideration and will be the subject of a future rulemaking.

Timetable:

Action	Date	FR Cite
NPRM	09/05/19	84 FR 46688
NPRM Comment Period End	12/04/19	
Final Rule	03/00/22	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AH81

Department of Health and Human Services (HHS)	Long-Term Actions
Food and Drug Administration (FDA)	

281. REQUIREMENTS FOR ADDITIONAL TRACEABILITY RECORDS FOR CERTAIN FOODS

Legal Authority: sec. 204 of the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353) (21 U.S.C. 2223(d)); sec. 701(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(a)); sec. 361 of the Public Health Service Act (42 U.S.C. 264)

Abstract: This rule will establish additional recordkeeping requirements for facilities that manufacture, process, pack, or hold foods that are designated as high-risk foods.

Timetable:

Action	Date	FR Cite
NPRM	09/23/20	85 FR 59984
NPRM Comment Period End	01/21/21	
NPRM Comment Period Extended	12/18/20	85 FR 82393
NPRM Comment Period End	02/22/21	
Final Rule	11/00/22	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Katherine Vierk, Director, Division of Public Health Informatics and Analytics, Department of Health and Human Services, Food and Drug Administration, 5001 Campus Drive, CPK1, Room 2B014, HFS–005, College Park, MD 20740

Phone: 240 402–2122

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RIN: 0910–AI44

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282. • POSTMARKETING SAFETY REPORTING REQUIREMENTS, PHARMACOVIGILANCE PLANS, AND PHARMACOVIGILANCE QUALITY SYSTEMS FOR HUMAN DRUG AND BIOLOGICAL PRODUCTS

Legal Authority: 42 U.S.C 262; 42 U.S.C. 264; 42 U.S.C. 300aa–25; 21 U.S.C. 321; 21 U.S.C. 351 to 353; 21 U.S.C. 355; 21 U.S.C. 360; 21 U.S.C. 371; 21 U.S.C. 374; ...

Abstract: The proposed rule would modernize FDA’s regulations on postmarketing safety reporting and pharmacovigilance for human drug and biological products, including blood and blood components, by

capturing important new safety-related information, improving the quality and utility of submitted reports, and supporting enhanced alignment with internationally harmonized reporting guidelines. Among other things, the proposed rule would require the submission of certain nonclinical and clinical data to FDA in a periodic safety report, rather than the annual report. The proposed rule also would require application holders for drug products and certain biological products to establish and maintain a pharmacovigilance quality system that reflects the application holder's unique needs and that may support a more streamlined, flexible approach to satisfying certain postmarketing safety reporting requirements.

Timetable:

Action	Date	FR Cite
NPRM	03/00/23	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Janice L. Weiner, Principal Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Avenue, Building 51, Room 6270, Silver Spring, MD 20993–0002

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RIN: 0910–AI61

Department of Health and Human Services (HHS)	Proposed Rule Stage
Centers for Medicare & Medicaid Services (CMS)	

283. ADMINISTRATIVE SIMPLIFICATION: MODIFICATIONS TO NCPDP RETAIL PHARMACY STANDARDS (CMS–0056)

Legal Authority: 42 U.S.C. 1320d to 1320d–9

Abstract: This proposed rule seeks to modify the currently adopted National Council for Prescription Drug Programs (NCPDP) standards to the Telecommunications Standard Implementation Guide Version F6 (F6); Batch Standard Implementation Guide version 15; and Batch Standard Subrogation Implementation Guide version 10.

Timetable:

Action	Date	FR Cite
NPRM	03/00/22	

Regulatory Flexibility Analysis Required: Yes

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Phone: 410 786–4466

Email: geanelle.herring@cms.hhs.gov

RIN: 0938–AU19

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284. MEDICARE ADVANTAGE AND MEDICARE PRESCRIPTION DRUG BENEFIT PROGRAM PAYMENT POLICY (CMS–4198)

Legal Authority: 42 U.S.C. 1395w

Abstract: This proposed rule would codify long-established Medicare Advantage and Part D payment policies that are outside the scope of the annual Advance Notice/Rate Announcement.

Timetable:

Action	Date	FR Cite
NPRM	05/00/22	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Jennifer Shapiro, Director, Medicare Plan Payment Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C1–13–18, 7500 Security Boulevard, Baltimore, MD 21244

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Email: jennifer.shapiro@cms.hhs.gov

RIN: 0938–AU59

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285. • CY 2023 REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE AND OTHER REVISIONS TO MEDICARE PART B (CMS–1770) (SECTION 610 REVIEW)

Legal Authority: 42 U.S.C. 1302; 42 U.S.C. 1395hh

Abstract: This annual proposed rule would revise payment polices under the Medicare physician fee schedule, and make other policy changes to payment under Medicare Part B. These changes would apply to services furnished beginning January 1, 2023. Additionally, this rule proposes updates to the Quality Payment Program.

Timetable:

Action	Date	FR Cite
NPRM	06/00/22	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Gift Tee, Director, Division of Physician Services, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, 7500 Security Boulevard, MS: C1–09–07, Baltimore, MD 21244

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RIN: 0938–AU81

286. • CY 2023 HOSPITAL OUTPATIENT PPS POLICY CHANGES AND PAYMENT RATES AND AMBULATORY SURGICAL CENTER PAYMENT SYSTEM POLICY CHANGES AND PAYMENT RATES (CMS–1772) (SECTION 610 REVIEW)

Legal Authority: 42 U.S.C. 1302; 42 U.S.C. 1395hh

Abstract: This annual proposed rule would revise the Medicare hospital outpatient prospective payment system to implement statutory requirements and changes arising from our continuing experience with this system. The proposed rule describes changes to the amounts and factors used to determine payment rates for services. In addition, the rule proposes changes to the ambulatory surgical center payment system list of services and rates. This proposed rule would also update and refine the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program.

Timetable:

Action	Date	FR Cite
NPRM	06/00/22	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AU82

287. • HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEMS FOR ACUTE CARE HOSPITALS; THE LONG–TERM CARE HOSPITAL PROSPECTIVE PAYMENT SYSTEM; AND FY 2023 RATES (CMS–1771–P) (SECTION 610 REVIEW)

Legal Authority: 42 U.S.C. 1302; 42 U.S.C. 1395hh

Abstract: This annual proposed rule would revise the Medicare hospital inpatient and long-term care hospital prospective payment systems for operating and capital-related costs. This proposed rule would implement changes arising from our continuing experience with these systems. In addition, the rule proposes to establish new requirements or revise existing requirements for quality reporting by specific Medicare providers.

Timetable:

Action	Date	FR Cite
NPRM	04/00/22	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Donald Thompson, Director, Division of Acute Care, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C4–01–26, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–6504

Email: donald.thompson@cms.hhs.gov

RIN: 0938–AU84

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288. • TRANSITIONAL COVERAGE FOR EMERGING TECHNOLOGIES (CMS–3421)

Legal Authority: 42 U.S.C. 263a; 42 U.S.C. 405(a); 42 U.S.C. 1302; 42 U.S.C. 1320b–12; ...

Abstract: This proposed rule would establish the criteria for an expedited coverage pathway to provide Medicare beneficiaries with faster access to innovative and beneficial technologies.

Timetable:

Action	Date	FR Cite
NPRM	10/00/22	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Lori Ashby, Senior Technical Advisor, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Clinical Standards and Quality, MS: S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244

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Email: lori.ashby@cms.hhs.gov

RIN: 0938–AU86

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289. • REQUIREMENTS FOR RURAL EMERGENCY HOSPITALS (CMS–3419) (SECTION 610 REVIEW)

Regulatory Plan: This entry is Seq. No. 66 in part II of this issue of the **Federal Register.**

RIN: 0938–AU92

Department of Health and Human Services (HHS)	**Final Rule Stage**
Centers for Medicare & Medicaid Services (CMS)	

290. DURABLE MEDICAL EQUIPMENT FEE SCHEDULE, ADJUSTMENTS TO RESUME THE TRANSITIONAL 50/50 BLENDED RATES TO PROVIDE RELIEF IN NON–COMPETITIVE BIDDING AREAS (CMS–1687) (SECTION 610 REVIEW)

Legal Authority: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(l)); Pub. L. 114–255, sec. 5004(b), 16007(a) and 16008

Abstract: This final rule responds to public comments on the interim final rule that published May 11, 2018 and extended the end of the transition period from June 30, 2016, to December 31, 2016 for phasing in adjustments to the fee schedule amounts for certain durable medical equipment (DME) and

enteral nutrition paid in areas not subject to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP). In addition, the interim rule amended the regulation to resume the transition period for items furnished from August 1, 2017, through December 31, 2018. The interim rule also made technical amendments to existing regulations for DMEPOS items and services to exclude infusion drugs used with DME from the DMEPOS CBP.

Timetable:

Action	Date	FR Cite
Interim Final Rule	05/11/18	83 FR 21912
Interim Final Rule Comment Period End	07/09/18	
Continuation Notice	04/26/21	86 FR 21949
Final Action to be Merged With 0938-AU38 and 0938-AU17	05/00/22	

Regulatory Flexibility Analysis Required: Yes

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Phone: 410 786–9671

Email: alexander.ullman@cms.hhs.gov

RIN: 0938–AT21

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291. REQUIREMENTS RELATED TO SURPRISE BILLING; PART II (CMS–9908)

Legal Authority: Pub. L. 116–260, Division BB, title I and title II

Abstract: This interim final rule with comment would implement additional protections against surprise medical bills under the No Surprises Act, including provisions related to the independent dispute resolution processes.

Timetable:

Action	Date	FR Cite
Interim Final Rule	10/07/21	86 FR 55980
Interim Final Rule Effective	10/07/21	
Interim Final Rule Comment Period End	12/06/21	
Reviewing Comments	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Deborah Bryant, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Consumer Information and Insurance Oversight, MS: W08–134, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 301 493–4293

Email: deborah.bryant@cms.hhs.gov

RIN: 0938–AU62

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292. • OMNIBUS COVID–19 HEALTH CARE STAFF VACCINATION (CMS–3415) (SECTION 610 REVIEW)

Regulatory Plan: This entry is Seq. No. 69 in part II of this issue of the **Federal Register.**

RIN: 0938–AU75

Department of Health and Human Services (HHS)	Long-Term Actions
Centers for Medicare & Medicaid Services (CMS)	

293. MOST FAVORED NATION (MFN) MODEL (CMS–5528) (SECTION 610 REVIEW)

Legal Authority: Social Security Act, sec. 1115A

Abstract: This final rule rescinds the Most Favored Nation Model interim final rule with comment period that appeared in the November 27, 2020, **Federal Register** .

Timetable:

Action	Date	FR Cite
ANPRM	10/30/18	83 FR 54546
ANPRM Comment Period End	12/31/18	
Interim Final Rule	11/27/20	85 FR 76180
Interim Final Rule Effective	11/27/20	
Interim Final Rule Comment Period End	01/26/21	
NPRM	08/10/21	86 FR 43618
NPRM Comment Period End	10/12/21	
Final Action	08/00/24	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Lara Strawbridge, Director, Division of Ambulatory Payment Models, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare and Medicaid Innovation, 7500 Security Boulevard, MS: WB–06–05, Baltimore, MD 21244

Phone: 410 786–7400

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RIN: 0938–AT91

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294. DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS AND SUPPLIES (DMEPOS) POLICY ISSUES AND LEVEL II OF THE HEALTHCARE COMMON PROCEDURE CODING SYSTEM (HCPCS) (CMS–1738) (SECTION 610 REVIEW)

Legal Authority: 42 U.S.C. 1395l; 42 U.S.C. 1395m; 42 U.S.C. 1395u; 42 U.S.C. 1395w–3

Abstract: This final rule responds to public comments on the proposed rule that published November 4, 2020, and establishes regulations for policy and program issues. Among the issues under consideration for this final rule are methodologies for adjusting the Medicare DMEPOS fee schedule amounts using information from the Medicare DMEPOS competitive bidding program for items furnished on the date immediately following the duration of the emergency period described in section 1135(g)(1)(B) of the Social Security Act; establishing procedures for making benefit category and payment determinations for new items and services that are durable medical equipment (DME), prosthetic devices, orthotics and prosthetics, therapeutic shoes and inserts, surgical dressings, or splints, casts, and other devices used for reductions of fractures and dislocations under Medicare Part B; classifying continuous glucose monitors (CGMs) as DME under Medicare Part B and establishing fee schedule amounts for these items and related supplies and accessories; and other issues in the proposed rule and interim final rules with comment period (IFC) that CMS issued on May 11, 2018 and May 8, 2020.

Timetable:

Action	Date	FR Cite
NPRM	11/04/20	85 FR 70358
NPRM Comment Period End	01/04/21	
Final Action	11/00/23	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Joel Kaiser, Director, Division of DMEPOS Policy, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C5–07–26, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–6506

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RIN: 0938–AU17

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295. HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEMS FOR ACUTE CARE HOSPITALS; THE LONG–TERM CARE HOSPITAL PROSPECTIVE PAYMENT SYSTEM; AND FY 2022 RATES (CMS–1752) (SECTION 610 REVIEW)

Legal Authority: 42 U.S.C. 1302; 42 U.S.C. 1395hh

Abstract: This rule finalizes the three remaining policies proposed for the Medicare hospital inpatient and long-term care hospital prospective payment systems for operating and capital-related costs. These policies include implementation of sections 126, 127, and 131 of the Consolidated Appropriations Act of 2020; changes in treatment of Medicaid Section 1115 waiver days for purposes of Medicare Disproportionate Share Hospital payments; and organ acquisition payment policies.

Timetable:

Action	Date	FR Cite
NPRM	05/10/21	86 FR 25070
NPRM Comment Period End	06/28/21	
Final Action	08/13/21	86 FR 44774
Final Action Effective	10/01/21	
Final Action Correction	10/20/21	86 FR 58019
2nd Final Action	05/00/24	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AU44

Department of Health and Human Services (HHS)	**Completed Actions**
Centers for Medicare & Medicaid Services (CMS)	

296. REQUIREMENTS FOR LONG–TERM CARE FACILITIES: REGULATORY PROVISIONS TO PROMOTE INCREASED SAFETY (CMS–3347) (COMPLETION OF A SECTION 610 REVIEW)

Legal Authority: secs. 1819 and 1919 of the Social Security Act; sec. 1819(d)(4)(B) and 1919(d)(4)(B) of the Social Security Act; sec. 1819(b)(1)(A) and 1919 (b)(1)(A) of the Social Security Act

Abstract: This final rule reforms the requirements that long-term care facilities must meet to participate in the Medicare and Medicaid programs in order to support the provision of safe care and preserve access to care.

Timetable:

Action	**Date**	**FR Cite**
NPRM	07/18/19	84 FR 34737
NPRM Comment Period End	09/16/19	
Withdrawn	08/04/21	

Regulatory Flexibility Analysis Required: Yes

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Email: diane.corning@cms.hhs.gov

RIN: 0938–AT36

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297. CY 2022 HOME HEALTH PROSPECTIVE PAYMENT SYSTEM RATE UPDATE, HOME INFUSION THERAPY SERVICES, AND QUALITY REPORTING REQUIREMENTS (CMS–1747) (COMPLETION OF A SECTION 610 REVIEW)

Legal Authority: 42 U.S.C. 1302; 42 U.S.C. 1395(hh)

Abstract: This annual final rule updates the home health prospective payment system payment rates and wage index. This rule also updates the home infusion therapy services payment rates. In addition, this rule implements changes to the Home Health Value-Based Purchasing Model and to the Home Health Quality Reporting Program.

Timetable:

Action	Date	FR Cite
NPRM	07/07/21	86 FR 35874
NPRM Comment Period End	08/27/21	
Final Action	11/09/21	86 FR 62240
Final Action Effective	01/01/22	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Brian Slater, Director, Division of Home Health and Hospice, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C4–07–07, 7500 Security Boulevard, Baltimore, MD 21244

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RIN: 0938–AU37

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298. FY 2022 INPATIENT PSYCHIATRIC FACILITIES PROSPECTIVE PAYMENT SYSTEM RATE AND QUALITY REPORTING UPDATES (CMS–1750) (COMPLETION OF A SECTION 610 REVIEW)

Legal Authority: 42 U.S.C. 1302; 42 U.S.C. 1395f; 42 U.S.C. 1395g; 42 U.S.C. 1395hh; 42 U.S.C. 1395ww(s)

Abstract: This annual final rule updates the prospective payment rates for inpatient psychiatric facilities (IPF) with discharges beginning on October 1, 2021. The rule also includes updates to the IPF Quality Reporting Program.

Timetable:

Action	Date	FR Cite
NPRM	04/13/21	86 FR 19480
NPRM Comment Period End	06/07/21	
Final Action	08/04/21	86 FR 42608
Final Action Effective	10/01/21	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Sherlene Jacques, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C5–04–27, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–0510

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RIN: 0938–AU40

299. CY 2022 REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE AND OTHER REVISIONS TO MEDICARE PART B (CMS–1751) (COMPLETION OF A SECTION 610 REVIEW)

Legal Authority: 42 U.S.C. 1302; 42 U.S.C. 1395hh

Abstract: This annual final rule revises payment polices under the Medicare physician fee schedule, and makes other policy changes to payment under Medicare Part B. These changes apply to services furnished beginning January 1, 2022. Additionally, this rule finalizes updates to the Quality Payment Program.

Timetable:

Action	Date	FR Cite
NPRM	07/23/21	86 FR 39104
NPRM Comment Period End	09/13/21	
Final Action	11/19/21	86 FR 64996
Final Action Effective	01/01/22	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AU42

300. CY 2022 HOSPITAL OUTPATIENT PPS POLICY CHANGES AND PAYMENT RATES AND AMBULATORY SURGICAL CENTER PAYMENT SYSTEM POLICY CHANGES AND PAYMENT RATES (CMS–1753) (COMPLETION OF A SECTION 610 REVIEW)

Legal Authority: 42 U.S.C. 1302; 42 U.S.C. 1395hh

Abstract: This annual final rule revises the Medicare hospital outpatient prospective payment system to implement statutory requirements and changes arising from our continuing experience with this system. The rule describes changes to the amounts and factors used to determine payment rates for services. In addition, the rule finalizes changes to the ambulatory surgical center payment system list of services and rates. This rule also updates and refines the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program.

Timetable:

Action	Date	FR Cite
NPRM	08/04/21	86 FR 42018
NPRM Comment Period End	09/17/21	
Final Action	11/16/21	86 FR 63458
Final Action Effective	01/01/22	

Regulatory Flexibility Analysis Required: Yes

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Phone: 410 786–9222

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RIN: 0938–AU43

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301. REQUIREMENTS RELATED TO SURPRISE BILLING; PART I (CMS–9909)

Legal Authority: Pub. L. 116–260, Division BB, title I and title II

Abstract: This interim final rule with comment implements certain protections against surprise medical bills under the No Surprises Act.

Completed:

Reason	Date	FR Cite
Interim Final Rule With Comment	07/13/21	86 FR 36872
Interim Final Rule Comment Period End	09/07/21	
Interim Final Rule Effective	09/13/21	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Lindsey Murtagh

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RIN: 0938–AU63

Department of Health and Human Services (HHS)	Proposed Rule Stage
Administration for Children and Families (ACF)	

302. UPDATING NATIVE EMPLOYMENT WORKS REQUIREMENTS (RULEMAKING RESULTING FROM A SECTION 610 REVIEW)

Legal Authority: 42 U.S.C. 612

Abstract: The rule would update NEW regulations at 45 CFR part 287 to avoid inconsistencies and reflect the changes that have been made to the NEW statute and Administration for Children and Families (ACF) grant policy and procedures since the current regulation's publication on February 18, 2000. In particular, the regulations need to address changes made in section 404(e) of the Social Security Act as

amended in 1999, Uniform Administrative Requirements, Cost Principles, and Audit Requirement for HHS Awards (45 CFR part 75) - Part 75 Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards, Public Law 106-107, the "Federal Financial Assistance Management, Improvement Act of 1999" (Nov. 20, 1999), and various minor technical changes. While some of these changes have been addressed and communicated to the public and grantees via program instructions and information memoranda, the regulations themselves are now inconsistent with current law and policy.

Timetable:

Action	Date	FR Cite
NPRM	06/00/22	

Regulatory Flexibility Analysis Required: No

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